



Complete Summary

GUIDELINE TITLE

The copper intrauterine device as long-term contraception.

BIBLIOGRAPHIC SOURCE(S)

The copper intrauterine device as long-term contraception. J Fam Plann Reprod Health Care 2004 Jan; 30(1):29-41; quiz 42. [119 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the [FDA Web site](#) for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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CONTRAINDICATIONS

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Unintended pregnancy
- Problems caused by or affecting intrauterine device insertion or usage (suspected perforation, lost threads, abnormal bleeding, pregnancy, infection, pain, etc.)

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations and good practice points regarding the use of a copper intrauterine device as long-term contraception

TARGET POPULATION

Women considering intrauterine devices as long-term contraception

INTERVENTIONS AND PRACTICES CONSIDERED

1. Clinical history including sexual history
2. Physical examination including bimanual pelvic examination, pulse, and blood pressure measurements, if indicated
3. Testing for sexually transmitted infections if appropriate
4. Assessment of medical eligibility for intrauterine device (IUD) use
5. Counseling women regarding risks associated with IUD insertion, symptoms of pelvic infection, and when to seek medical advice
6. Intravenous antibiotic prophylaxis for women with previous endocarditis or with a prosthetic heart valve
7. Using IUDs containing at least 300 mm² of copper
8. Procedures and documentation required for IUD insertion including
 - Chaperones
 - Assistants
 - Emergency equipment
 - Documentation of pre-insertion counseling and the insertion procedure
 - Cervical cleansing (considered but not recommended)
 - Analgesia, topical anesthesia, or intracervical block if requested
 - Use of forceps and assessing the length of uterine cavity
 - Training for doctors wishing to obtain a letter of competence in intrauterine techniques
9. Follow-up visit
10. Management of IUD problems
11. Removal of IUD

MAJOR OUTCOMES CONSIDERED

- Medical eligibility criteria for the use of intrauterine contraceptive device (IUD)
- Risks, benefits, safety, and efficacy of IUD
- Cumulative pregnancy rate (failure rate) for various intrauterine devices

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for: MEDLINE (CD Ovid version) (1996-2003); EMBASE (1996-2003); PubMed (1996-2003); the Cochrane Library (to September 2003), and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms, and text

words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials relevant to copper-bearing intrauterine contraception. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO), and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on intrauterine devices (IUD's) for long-term contraception, which was identified and appraised in the development of this Guidance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based of levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

What should a clinician assess before inserting an intrauterine device (IUD)?

1. After counselling, an IUD is a safe contraceptive choice for the majority of women (Grade C).
2. After counselling about other contraceptive methods, women who are assessed as at higher risk of STI may still choose to use an IUD (Grade C).

After considering other contraceptive methods, a woman may use an IUD within 3 months of treated pelvic infection, provided she has no signs and symptoms (Good Practice Point).

3. Women who are human immunodeficiency virus (HIV)-positive may be offered an IUD after testing for bacterial sexually transmitted infections (STIs) (Grade B).
4. There are no drugs that are known to affect IUD use and efficacy (Grade C).
5. A bimanual pelvic examination should be performed before inserting an IUD (Grade C).

6. STI risk assessment (history and examination) should be performed for all women considering an IUD (Grade C).
7. Women assessed to have a higher risk of STI should be offered testing for Chlamydia trachomatis (as a minimum) prior to IUD insertion (Grade C).

Women assessed to have a higher risk of STI may also be offered testing for Neisseria gonorrhoea prior to IUD insertion, depending on its local prevalence (Good Practice Point).

There is no indication to test for other lower genital tract organisms in asymptomatic women attending for IUD insertion (Good Practice Point).

Ideally, for women assessed as at higher risk of STI, the results of tests should be available and appropriate treatment provided prior to IUD insertion (Good Practice Point).

For women assessed as at higher risk of STI, if results are not available and IUD insertion cannot be delayed, the use of prophylactic antibiotics may be considered (Good Practice Point).

Pulse rate should be measured and documented post-IUD insertion (Good Practice Point).

8. Prophylactic antibiotics are not recommended for routine IUD insertion (Grade A).
9. Women with previous endocarditis or with a prosthetic heart valve require intravenous antibiotic prophylaxis to protect against bacterial endocarditis during IUD insertion or removal (Grade C).

When prophylaxis against bacterial endocarditis is required, clinicians should refer to the British National Formulary (BNF) for the most up-to-date regimen and ensure the IUD procedure takes place in an appropriate setting (Good Practice Point).

What do women need to know when considering an IUD?

10. Women should be informed that the primary mode of action of an IUD is prevention of fertilisation (Grade B).
11. Women should be advised of the low failure rate of IUDs (i.e. around 1%) (Grade C).
12. IUDs containing at least 300 mm² of copper should be used as they have the lowest failure rates (Grade A).

IUDs such as T-Safe Cu380A represent a reversible alternative to female sterilisation (Good Practice Point).

13. IUDs with the longest licensed duration of use should be used to minimise the established risks associated with re-insertion (Grade C).

Women should be given information on the device inserted and its licensed duration of use to avoid unnecessary early removal. This information should also be documented in the case notes (Good Practice Point).

14. Women should be advised that a small increase in risk of pelvic infection occurs in the 20 days following IUD insertion but the risk is the same as the non-IUD-using population thereafter (Grade A).
15. Women should be informed of the symptoms of pelvic infection and advised how and where to seek medical help if these occur, particularly in the first 3 to 4 weeks after insertion (Grade C).
16. Women should be informed that the overall risk of ectopic pregnancy is reduced with IUD use compared to using no contraception (Grade B).
17. Women may be informed that previous use of an IUD does not affect fertility (Grade C).
18. Women should be advised that the most likely cause of IUD failure is expulsion. The risk of this happening is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion (Grade B).
19. Women may be informed that uterine perforation occurs in fewer than 1 in 1,000 insertions (Grade B).

Women should be offered instruction on how to check for the IUD and its threads and advised that if they are unable to feel them it may be that the device has been expelled. Alternative contraception should then be used until medical advice has been sought (Good Practice Point).

20. Women should be informed that menstrual abnormalities (including spotting, light bleeding, heavy or longer menstrual periods) are common in the first 3 to 6 months of IUD use (Grade C).
21. Women should be informed that unacceptable bleeding is one of the most common reasons for requesting IUD removal (Grade B).

Women should be advised to seek medical advice, to exclude infection and gynaecological pathology, if menstrual abnormalities persist beyond the initial 6 months of use (Good Practice Point).

22. Women should be informed that dysmenorrhoea is a common reason for requesting IUD removal (Grade B).
23. Women may be informed that there is no evidence of an increase in reproductive tract cancer with IUD use (Grade B).
24. An IUD can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant (Grade C).

Recommendation for timing of IUD Insertion

| Circumstances when IUD can be inserted | Recommendations for timing of IUD insertion |
|--|---|
| Women with regular menses | If pregnancy can be excluded an IUD can be inserted at any time during the menstrual cycle. Pregnancy can be reasonably excluded if there are no symptoms or signs of |

| Circumstances when IUD can be inserted | Recommendations for timing of IUD insertion |
|--|---|
| | <p>pregnancy and any of the following criteria are met:</p> <ul style="list-style-type: none"> • No sexual intercourse since last normal menses • Correct and consistent use of a reliable method of contraception • Within 7 days of starting normal menses <p>Up to 5 days after the first episode of sexual intercourse in a menstrual cycle or up to 5 days after the earliest calculated time of ovulation in a regular cycle^a</p> |
| Women who are amenorrhoeic | Any time at the woman's convenience, if it is reasonably certain that she is not pregnant (as above) |
| Women who are postpartum | For women who are fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum (including Caesarean section) an IUD can be inserted within 48 hours of delivery ^b or 4 or more weeks postpartum ^c |
| Following termination of pregnancy | At the time of a first- or second-trimester surgical termination of pregnancy (TOP) ^d . Following medical or surgical termination suggested within the first 48 hours; otherwise wait until 4 or more weeks post-termination ^e |
| Switching from another method of contraception | Any time if it is reasonably certain that the woman is not pregnant (as above). There is no need to wait for the next menstrual period |

^a An IUD can be inserted up to 5 days after the first episode of unprotected sex or up to 5 days after the earliest expected date of ovulation.

^b The risk of uterine perforation is increased if an IUD is inserted between 49 hours and up to 4 weeks postpartum.

^c Evidence suggests an IUD may be inserted from 4 weeks postpartum.

^d The risk of expulsion is greater when an IUD is inserted immediately following second-trimester TOP but the benefits generally outweigh risks.

^e Advice regarding IUD insertion following medical TOP is in keeping with postpartum insertion.

25. An IUD may be inserted safely 4 or more weeks postpartum (Grade C).

26. An IUD can be inserted safely immediately following a first-trimester or second-trimester TOP (Grade C).

What procedures and documentation are required for IUD insertion?

27. A chaperone should be offered to all women having a pelvic examination and the offer documented in the case notes, together with the chaperone's identity, if accepted (Grade C).
28. An appropriately trained assistant should be present during IUD insertion to help in the event of an emergency (Grade C).
29. Emergency equipment must be available in all settings where IUDs are inserted and local referral protocols must be in place for patients requiring further medical input (Grade C).
30. Clinicians involved in IUD insertions should be trained and attend regular updates in dealing with likely emergencies (Grade C).
31. Details of pre-insertion counselling and the insertion procedure should be clearly documented in patient records (Grade C).

Cleansing the ectocervix prior to IUD insertion is not essential (Good Practice Point).

A "no-touch" technique should be used when sounding the uterine cavity and inserting an IUD. Sterile gloves are not required (Good Practice Point).

Pain relief prior to, and during, IUD insertion should be discussed with women and administered appropriately (Good Practice Point).

The use of topical anaesthesia or intracervical block for IUD procedures should be discussed with women and provided if requested (Good Practice Point).

32. A pair of forceps (such as Allis or tenaculum) should be used, and an assessment of the length of the uterine cavity made, to reduce the risk of perforation and facilitate fundal placement of the IUD (Grade C).

Who can insert an IUD?

33. Clinicians who insert IUDs are responsible for ensuring that they are appropriately trained and maintain their clinical competence (Grade C).

What follow-up is required following IUD insertion?

34. A follow-up visit should be advised after the first menses, or 3 to 6 weeks, after IUD insertion (Grade C).
35. Women should be advised to seek medical help at any time if they develop symptoms of pelvic infection, pain, persistent menstrual abnormalities, missed period, or non-palpable threads (Grade C).

How are IUD problems managed?

If uterine perforation at insertion is suspected, the procedure should be stopped and vital signs and level of discomfort monitored until stable. Urgent and specific follow-up should be arranged to include ultrasound scan and/or plain abdominal X-ray to locate the device if it has been left in situ (Good Practice Point).

36. IUD retrievers (such as Emmett and Retrievet) can be effective in locating threads (Grade A).

If no threads are seen and uterine placement of the IUD cannot be confirmed clinically, an ultrasound scan should be arranged to locate the device and alternative contraception recommended (Good Practice Point).

If an ultrasound scan cannot locate the IUD and there is no definite evidence of expulsion, a plain abdominal X-ray should be arranged to identify an extrauterine device (Good Practice Point).

37. Gynaecological pathology and infection should be excluded if abnormal bleeding persists beyond the first 6 months following IUD insertion (Grade C).
38. Non-steroidal anti-inflammatory drugs (NSAIDs) (mefenamic acid) can be used to treat spotting, light bleeding, and heavy or prolonged menstruation. Antifibrinolytics (tranexamic acid) may be used for heavy or prolonged menstruation (Grade A).
39. Most pregnancies occurring in women using an IUD will be intrauterine, but ectopic pregnancy must be excluded (Grade C).
40. Women who become pregnant whilst using an IUD should be informed of the increased risks of second-trimester miscarriage, preterm delivery, and infection if the IUD is left in situ (Grade B).
41. Women who are pregnant with an IUD in situ, and who wish to continue with the pregnancy, should be informed that, when possible, IUD removal would reduce adverse outcomes. However, removal itself carries a small risk of miscarriage (Grade C).
42. Whether or not the IUD is removed, a pregnant woman should be advised to seek medical care if she develops heavy bleeding, cramping pain, abnormal vaginal discharge, or fever (Grade C).

If there is no evidence that the IUD was expelled prior to pregnancy, it should be sought at delivery or termination of pregnancy (TOP) and, if not identified, a plain abdominal X-ray should be arranged to determine if the IUD is extrauterine (Good Practice Point).

Removal of an IUD

43. An IUD should be removed during or after the menstruation following sterilisation (Grade C).

When switching to a hormonal contraceptive, this should be initiated prior to IUD removal to maintain contraceptive protection (Good Practice Point).

For women who wish to become pregnant, an IUD can be removed at any time in the menstrual cycle (Good Practice Point).

An IUD can be removed at any time in the cycle if it is to be replaced immediately with another IUD. However, women should be advised to use condoms or abstain from sexual intercourse for 7 days before the exchange, in case a new IUD cannot be inserted immediately (Good Practice Point).

An IUD can be replaced by an intrauterine system (IUS) at any time in the menstrual cycle but women should be advised to use condoms or abstain from

sexual intercourse for 7 days before removal of the IUD and for a further 7 days after insertion of the IUS (Good Practice Point).

44. Asymptomatic IUD users with actinomyces-like organisms (ALOs) detected on a cervical smear should be advised there is no reason to remove the IUD unless signs or symptoms of infection occur (Grade B).
45. For IUD users with pelvic inflammatory disease (PID), appropriate antibiotics should be started. There is no need to remove the IUD unless symptoms fail to resolve (Grade B).

Postmenopausal women should be advised to have their IUDs removed 1 year after their last menstrual period (LMP) if this occurs when they are over the age of 50 years, and 2 years after their LMP if aged less than 50 years (Good Practice Point).

Definitions

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of a copper intrauterine device for long-term contraception

POTENTIAL HARMS

Risks associated with intrauterine device (IUD) as long-term contraception:

- There is a small increase in risk of pelvic infection in the 20 days following IUD insertion.
- The risk of IUD expulsion is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion.
- Uterine perforation occurs in fewer than 1 in 1,000 insertions.
- Menstrual abnormalities are common in the first 3 to 6 months of IUD use.
- Dysmenorrhea is a common reason for requesting IUD removal.
- The failure rate is around 1%.

Risks associated with IUD usually outweigh the benefits in the following circumstances:

- Postpartum insertion between 48 hours and 4 weeks postpartum in women who are breastfeeding, not breastfeeding, or post-Caesarean section
- Current benign gestational trophoblastic disease
- Ovarian cancer
- Continuation in women with known pelvic tuberculosis (TB)

CONTRAINDICATIONS

CONTRAINDICATIONS

The copper intrauterine device as long-term contraception should not be used in the following circumstances:

- Pregnancy
- Puerperal sepsis
- Immediate post-septic abortion
- Distorted uterine cavity (any congenital or acquired abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion) including uterine fibroids
- Insertion before evaluation of unexplained vaginal bleeding which is suspicious for serious conditions
- Current malignant gestational trophoblastic disease
- Insertion in women with cervical cancer who are awaiting treatment, or endometrial cancer
- Insertion for women with a current sexually transmitted infection (STI) or pelvic inflammatory disease (PID)
- Insertion in women with known pelvic tuberculosis (TB)

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

The copper intrauterine device as long-term contraception. J Fam Plann Reprod Health Care 2004 Jan; 30(1): 29-41; quiz 42. [119 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jan

GUIDELINE DEVELOPER(S)

Faculty of Family Planning and Reproductive Health Care - Professional Association

SOURCE(S) OF FUNDING

Faculty of Family Planning and Reproductive Health Care

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

Print copies: Available from the Faculty of Family Planning and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for the intrauterine device as long-term contraceptive developed by the Faculty of Family Planning and Reproductive Health are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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